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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Publication Date 115-02

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Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 17, 2002, from 8:30 a.m. to 5 p.m.

Location: Bethesda Marriott Hotel, 5151 Pooks Hill Rd., Bethesda, MD.

Contact Person: Jody G. Sachs or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will review and discuss safety and efficacy and proposed indications for the product, FluMist, a cold-adapted, live attenuated, oc02290

trivalent influenza vaccine for the prevention of influenza sponsored by MedImmune Vaccines, Inc.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jody G. Sachs or Denise H. Royster at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated:

November 7, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for

External Relations.

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